IN THE UNITED STATES COURT FOR THE DISTRICT OF UTAH

CENTRAL DIVISION

UTAH MEDICAL PRODUCTS, Plaintiff, vs. MARK B. MCCLELLAN, Defendant.	**OPINION DENYING MOTION TO COMPEL DOCUMENTS** Case No. 2:03-CV-00525 PGC

This court on December 18, 2003, denied Utah Medical Products' ("Utah Medical's") motion to compel the production of documents. This opinion explains the court's conclusions.

Background

In March 2003, Utah Medical filed an application with the U.S. Food and Drug Administration ("FDA") requesting that it issue Certificates to Foreign Governments allowing the export of some of the company's medical devices to Korea and Ecuador. The FDA denied the application for the Certificates on April 1, 2003.

In the action pending before the court, Utah Medical alleges the FDA denial was arbitrary and capricious or in violation of law. In June 2003, Utah Medical filed a motion requesting the timely production of the administrative record and justification of any claim of privilege. This court granted that motion, ordering the production of the administrative record by August 2003

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and requiring the FDA to create a document log of any documents it withheld from the administrative record under a claim of privilege. The FDA complied with the court's order and produced a fifteen-volume administrative record. The FDA withheld all or a part of seven documents on grounds of privilege.

Utah Medical Products then objected to the FDA's decision to withhold four documents and redact three documents in the administrative record arguing that the documents are privileged and show possible agency misconduct. The court views this issue differently. It appears that during the 2003 inspection and subsequent interactions, a hostile, non-productive dialogue ensued between Utah Medical and the FDA. Both parties may well have miscommunicated and misinterpreted each other's actions. These miscues, however, do not warrant the release of the seven documents in question. After briefing and an *in camera* review of the seven documents in question, this court denies the motion to compel.

Standard of Review

The standard of review of agency action under the Administrative Procedures Act ("APA") allows this court to disturb FDA action only if the FDA acted in a matter that was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[1] This court must accord the FDA even greater deference when its decision is based on the evaluation of scientific information within its area of technical expertise.[2] Review of administrative decision is

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[1] 5 U.S.C. § 706(2)(A).

[2] *Bristol-Myers Squibb Co. v. Shalala*, 923 F.Supp. 212, 216 (D.D.C. 1996)(*citing Federal Power Commission v. Florida Power & Light Co.*, 404 U.S. 453, 463 (1972)).

generally limited to a review of the administrative record, and this court must presume the regularity of agency proceedings, unless there exists *clear* evidence to the contrary.[3]

Discussion

The court will now discuss each of the seven documents in turn.

I. Document 1 - Attachment to the 2003 Establishment Inspection Report

The FDA provided Utah Medical with the 2003 Establishment Inspection Report ("EIR") in its entirety, except for this one attachment. Prepared by Patrick Weixel, a Consumer Safety Officer at the Center for Devices and Radiological Health ("CDRH") at the FDA's headquarters in Maryland, the attachment has no date and is entitled "Inspectional Guidance." The parties agree the FDA intended this document for the FDA Investigators who conducted the 2003 inspection of Utah Medical's Midvale, Utah facilities. The document states the author's opinions regarding Utah Medical's response to the findings of the 2002 inspections and suggests issues for the 2003 inspection.

Deliberative Process Privilege

The FDA seeks to withhold this document on the grounds that the deliberative process privilege applies. The deliberative process privilege protects documents that may contain ". . . advisory opinions and recommendations or reflecting deliberations . . . . "[4] This added protection

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[3] *Bar MK Ranches v. Yeutter,* 994 F.2d 735, 740 (10th Cir. 1993)(emphasis added, citations omitted).

[4] *Mead Data Central, Inc., v. United States Dept. of Air Force,* 566 F.2d 242, 256 (D.C.Cir. 1977).

"seeks to protect the integrity of governmental decision making."[5] The privilege rests on the "obvious" conclusion that officials will not communicate candidly and frankly if each remark may end up as "front page news."[6]

Courts have mandated two requirements for a document to qualify for the deliberative process privilege. The documents must be both "pre-decisional" and "deliberative."[7] A document is "pre-decisional" if it was prepared to assist an agency decision maker in arriving at a decision.[8] A document is "deliberative" if it relates to the formulation of agency policy.[9] The deliberative process privilege extends to "recommendations, draft documents, proposals, suggestions, and other subjective documents which reflect the personal opinions of the writer rather than the policy of the agency."[10]

Evaluating whether a document qualifies for the deliberative process privilege requires a two-step process. First, the court must determine whether the privilege applies to the documents at issue. Then the court must balance the parties' interests to determine whether the documents should be produced, even if they are deliberative. The FDA bears the initial burden of

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[5] *United States v. Furrow,* 100 F.Supp.2d 1170, 1174 (C.D.Cal. 2000).

[6] *Casad v. U.S. Dept. of Health and Human Services,* 301 F.3d 1247, 1251 (10th Cir. 2002)(internal citations omitted).

[7] *Access Reports v. Department of Justice,* 926 F.2d 1192, 1194-95 (D.C.Cir. 1991).

[8] *Hopkins v. U.S. Dept. of Housing and Urban Development,* 929 F.2d 81, 84 (2nd Cir. 1991).

[9] *Id.*

[10] *Grand Cent. Partnership, Inc., v. Cuomo,* 166 F.3d 473, 482 (2nd Cir. 1999)(internal citations omitted).

establishing that the deliberative process privilege applies; Utah Medical bears the burden of showing its need for the documents outweighs the government's interest in non-disclosure.[11]

The privilege applies to Document 1 because it is both pre-decisional and deliberative. Document 1 is pre-decisional because Mr. Weixel prepared Document 1 to assist the FDA in determining whether to seek an enforcement action against Utah Medical and what type of action (if any) the FDA should take. Document 1 is deliberative because Mr. Weixel recommended issues for the inspectors to evaluate and document upon their visit to Utah Medical in 2003.

Utah Medical does not argue that Document 1 is post-decisional or non-deliberative. Instead, it contends that the privilege should not apply to Document 1 because (1) it is a communication between a superior agency official and an inferior official; (2) the privilege has been waived; and (3) there were instances of misconduct in the investigation of Utah Medical. If true, these allegations might support the conclusion that the deliberative process privilege should not apply. These allegations, however, are not true.

Superior Agency Official

Utah Medical argues that the deliberative process privilege should not apply because Mr. Weixel was a "superior agency official" communicating to an "inferior agency official" (the FDA investigators) and therefore Document 1 is not protected by the deliberative process privilege.[12] This claim misstates Mr. Weixel's role. Mr. Weixel has no superior relationship to any FDA

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[11] *See United States v. Farley,* 11 F.3d 1385, 1389 (7th Cir. 1993).

[12] *See Casad,* 301 F.3d at 1252; *see also Taxation With Representation Fund v. IRS,* 646 F.2d 666, 681 (D.C.Cir. 1981); *Schlefer v. United States,* 702 F.2d 233, 238 (D.C.Cir. 1983).

investigators. The FDA has five "Centers" that focus on certain products. Mr. Weixel works for one of the centers – the CDRH – which focuses on devices and radiological health. The FDA also has an "Office of Regulatory Affairs" and a "Division of Field Investigations." These offices include field offices that focus on a particular geographic region, and are not part of any of the Centers. Ms. Karen Coleman, of the Division of Field Investigations, and Ms. Ricki Chase-Off of the Denver District Office conducted the 2003 inspection work at Utah Medical. Mr. Weixel does not hold a supervisory position regarding either one of these individuals. In fact, he doesn't even work in the same division of the FDA. Therefore, Utah Medical's argument that Document 1 should be released due to the "superior" official argument is without merit.

Waiver

Utah Medical also argues that the FDA's decision to release the entire 2003 EIR, which included the investigators' response to the Inspectional Guidance, amounted to a waiver of the deliberative process privilege.[13] However, release of a document does not release all "related materials."[14] The *response* to the Inspectional Guidance, was part of the 2003 EIR, and is an entirely separate document than the Inspectional Guidance written by Mr. Weixel. Disclosing the portions of the 2003 EIR that disclosed the *responses* to the Guidance does not reveal Mr. Weixel's analysis of the issues facing Utah Medical nor its recommendation of issues for evaluation and follow-up in the 2003 inspection.

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[13] *See e.g. Peck v. United States,* 514 F.Supp. 210, 212 (S.D.N.Y. 1981); *and Moore-McCormack Lines, Inc., v. I.T.O. Corp. of Baltimore,* 508 F.2d 945, 948 (4th Cir. 1974).

[14] *In re Sealed Case,* 121 F.3d 729, 741 (D.C.Cir. 1997); *see Morrison v. U.S. Dept. of Justice,* 1988 WL 47662 at *1 (D.D.C. Apr. 29, 1988).

Allegations of Misconduct

Utah Medical raises a final argument as to Document 1: that the deliberative privilege does not apply when there is a factual basis for the belief that the information sought might reveal misconduct on the government's part.[15] Specifically Utah Medical points to their expert's report and argues misconduct occurred during the 2003 inspection and the creation of the 2003 EIR. Utah Medical raises four alleged examples of misconduct by the two FDA investigators who visited Utah Medical: (1) their misinterpretation of Utah Medical's compliance with International Quality Standards; (2) their interpretation of the documentation of Utah Medical's Extrusion and Injection Molding Processes; (3) their conclusions regarding Comparative Resistance Studies performed by Utah Medical; and (4) their possible violations of FDA policy. All four of these allegations highlight the miscommunication that occurred during the 2003 inspection at Utah Medical. None of these items, however, sufficiently supports a claim of misconduct on the part of the FDA to warrant disclosure of this document.

a. Utah Medical's Compliance with International Quality Standards

Utah Medical argues that the 2003 EIR suggests that the International Organization for Standardization (ISO) did not register Utah Medical as having complied with ISO standards. Utah Medical argues that their ISO 9001 registration was voluntarily discontinued so that it could seek registration under the "more stringent" ISO 13485 standards and that the EIR creates a

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[15] *Alexander v. FBI,* 186 F.R.D. 154, 164 (D.D.C. 1999)(*quoting In re Sealed Case,* 121 F.3d at 746.

misimpression.[16] Notably, Utah Medical does not argue that the EIR language was factually inaccurate. The language was arguably confusing. However, this does not support a conclusion that Investigator Chase-Off participated in some sort of "misconduct." The statements in the EIR were in the context of other points in the "Management Review" section of the EIR, specifically the "Additional Information" section. These comments did not provide any basis for any observations of noncompliance by Utah Medical. This is not the material from which a claim of misconduct can be manufactured.

In a brief argument, in a footnote, Utah Medical's expert, Dr. McDonnell, argues that the FDA should not have obtained the "agenda" that provided the ISO and NSAI information, and that even asking for this document is misconduct. Ms. Chase-Off requested the management review agenda only to ensure that Utah Medical was complying with the Quality System Regulations' requirement that mandated that Utah Medical establish and maintain procedures for implementing corrective and preventative action. When a device had a problem, the Quality System Regulations required that Utah Medical submit relevant information on identified quality problems.[17] The agenda requested was merely a device to allow the FDA inspector to determine whether or not quality data was being reviewed by Utah Medical's management. There was no misconduct involved in pursuing this avenue of investigation.

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[16] Memorandum in Support of Motion to Compel Production of Administrative Record Documents, p. 7-8.

[17] 21 C.F.R. § 820.100(a)(7).

As to Utah Medical's assertions that it "otherwise informed" Investigator Chase-Off it was seeking the more stringent ISO 13485 registration, Utah Medical points to no document that indicates the FDA had this information. Inferences that Utah Medical's expert draws from accurate statements do not rise to the level of misconduct to warrant waiver of the deliberative process privilege.

b. Extrusion and Injection Molding Processes Documentation

Utah Medical also argues that the following section of the 2003 EIR supports its allegations of misconducts:

> Molding Operations: The firm could not provide any evidence they had ever validated their extrusion or injection molding operations. They claimed it was done and they were given several days to look through archive files. They never submitted anything for review by the closeout and confirmed they could not find anything.[18]

However, it appears that Utah Medical misunderstands what the FDA meant in this passage. This passage discusses whether or not Utah Medical had adequately validated its molding process. "Validation" involves examination and the provision of *objective* evidence that the particular requirements for a specific intended use can be consistently fulfilled.[19] *Process Validation* refers to the process of ensuring that a medical device manufacturing *process* consistently produces a result or product that meets predetermined specifications.[20] Process Validation, and Validation are two distinct approvals required from the FDA. Utah Medical argues that the statistical process control it used was "more stringent" than the Process Validation

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[18] Exhibit 9.

[19] 20 C.F.R. § 820.3(z) (emphasis added).

[20] *See* 21 C.F.R. § 820.3(z)(1).

required by the Quality System Requirements. However, statistical process control works for *monitoring* a process that has been first *validated.* Utah Medical needed to submit the information as to whether its injection and molding process had been validated, before, or in conjunction with the submission of the statistical data.[21] It appears what occurred between the FDA and Utah Medical was a misunderstanding, not any misconduct on the agency's part.

c. Comparative Resistance Study

Utah Medical's third allegation of misconduct rests on the fact that its expert is "troubled" by a portion of the 2003 EIR that criticizes Utah Medical for failing to conduct a comparative resistance study on its UP-500 product line. Utah Medical claims that the FDA's failure to include in the EIR a "new study" that Utah Medical performed while the investigation was on-going was misconduct.

Manufacturers of sterile devices are required to validate their sterilization processes.[22] Based upon their own outside sterilization expert, Utah Medical used a comparative resistance study to support its sterilization processes adequately sterilized the UP-500 product lines. A comparative resistance study determines whether a previously validated sterilization process used on a particular product will adequately sterilize a second product – because that product is easier to sterilize than the previously validated device. The FDA's inspector did not agree with Utah Medical's conclusions from their comparative resistance study on the UP-500 product line. The

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[21] *See* 21 C.F.R. § 820.75(a)&(b).

[22] *See* 21 C.F.R. § 820.75(a); *see also* The Medical Devices: Current Good manufacturing Practice (CGMP) Final Rule, 61 Fed. Reg. 52602, 52631 (Oct. 7, 1996).

fact that Utah Medical's expert and the FDA's inspector disagreed does not rise to the level of misconduct.

During the investigation, to address FDA concerns, Utah Medical agreed to conduct an additional comparative resistance study. Utah Medical used an outside expert to perform the study while the FDA inspection was still ongoing. In the 2003 EIR, the FDA did not mention the new study's results. The preliminary results of the new study were emailed to the FDA inspector on March 11, 2003. This email contained only minimal information and did not include supporting documentation. The FDA did not receive the final study report until April 11, 2003, after the completion of the March 31, 2003. This court does not find the FDA's failure to include a preliminary report in its 2003 EIR as evidence of misconduct sufficient to warrant penetrating the privilege asserted.

d. Alleged Violations of Agency Policy

Utah Medical argues that the investigators did not provide them with "fair notice" of any "objectionable conditions" they observed and this alleged misconduct warrants the release of Document 1. It argues that FDA policy requires investigators to discuss their observations when the FDA 483 (the form that lists objectionable observations by inspectors) is issued. This policy obviously allows companies subject to inspections the opportunity to correct any problems while the FDA is present at their facilities.

To give Utah Medical notice of potential problems, the FDA inspectors held a lengthy six hour close-out meeting with various Utah Medical executives. The transcripts of this meeting were included as an exhibit to the 2003 EIR. Utah Medical does not specify what should have

been discussed at the close-out meeting that was not. The FDA discussed at length their concerns at Utah Medical. The possible failure to mention *all* of the concerns before issuance of the FDA 483 does not amount to misconduct. Investigators are mandated to report *all* significant objectionable conditions in the FDA 483.[23] Furthermore, the Investigations Operations Manual is designed to be a reference manual for investigators, and other FDA employees. This manual does not confer any rights, privileges or immunities on any person.[24] A mere claim that things were missed in the final six-hour closeout meeting that were later included in the FDA 483 does not rise to the level of misconduct.

Balance of Interests

Finally, Utah Medical asserts even if the deliberative process privilege applies, the balance of interests nonetheless favors the disclosures of Document 1. Many factors influence the balancing test, including: (1) the relevance of the evidence; (2) the availability of other evidence; (3) the seriousness of the litigation; (4) the role of the government; and (5) the extent to which disclosure would hinder frank and independent discussion regarding contemplated policies and decisions.[25] Document 1 is potentially relevant to Utah Medical's claims, and obviously this is serious litigation. However, extensive other evidence – including several years of EIR's, a fifteen-volume administrative record, the FDA's 483 forms which explained in detail

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[23] Investigations Operations Manual, § 512.

[24] McDonnell Dec. Exh. 2.

[25] *See, e.g, In re Sealed Case,* 121 F.3d at 737,738; *Redland Soccer Club, Inc., v. Dept. of Army of U.S.*, 55 F.3d 827, 854 (3rd Cir. 1995), *cert. denied*, 516 U.S. 1071 (1996); *K.L. v. Edgar,* 964 F.Supp. 1206, 1209 (N.D.Ill. 1997).

the FDA's concerns with Utah Medical, and a six-hour meeting at the conclusion of the 2003 inspection – all provided Utah Medical with a clear explanation as to why the FDA denied its application for Certificates to Foreign Governments. Finally, Document 1 reflects the very type of forthright discussion that needs to occur within an agency to help formulate policy and determine whether or not enforcement action is appropriate. Releasing the document could significantly chill the FDA's deliberative process. For all these reasons, the court finds that the balance of interests tips decidedly in favor of non-disclosure of the document.

II. Documents 2, 3, 7 - Redacted Endorsement Pages from the 2001-2003 EIRs

These three documents present similar issues. In all three documents, the FDA redacted: (1) "Inspection Conclusions," "District Decision Type," and "Remarks" fields for each of the inspections; (2) opinions, evaluations, and recommendations of the investigator regarding whether "corrective action" by Utah Medical was needed on the various issues covered during the inspection; (3) the inspector's recommendation of "official action indicated," "voluntary action indicated," or "no action indicated;" and (4) what type of corrective action by Utah Medical was needed and what "Suggested Actions" were recommended.

This redacted information again easily falls within the deliberative process privilege. The information is pre-decisional; the investigators did not make the final decision whether or not to proceed with enforcement against Utah Medical. It is also deliberative in that the Inspectors prepared their reports to give their opinions as to whether Utah Medical operated in compliance with the relevant Quality System Regulations.

Utah Medical also claims that the redacted information merely reflects the "conclusions" of the investigators and therefore does not merit redaction. However, it is undisputed that the investigators involved in the Utah Medical on-site evaluations did not make that final decision as to what the FDA would ultimately chose to do in regards to Utah Medical. This decision rested in the hands of the Compliance Branch of the Denver District Office. Because the redacted information was both pre-decisional and deliberative it was properly protected from disclosure by the FDA.

To gain access to the materials, Utah Medical repeats its "misconduct" argument. For the same reasons discussed above it does not apply to this redacted information.

Finally, the balancing test does not favor release of the redacted information. Again, the missing information is possibly relevant to Utah Medical's claims. However, as stated earlier, the administrative record, the EIR's, and the lengthy close-out meeting provided an explanation to Utah Medical for the subsequent denial of certificates. The seriousness of this litigation is unquestioned, as is the role of the FDA in determining the safety of these medical products for foreign shipment. But once again, the missing information reflects recommendations, not a conclusive determination of final agency action. This type of frank inter-agency dialogue is exactly what the deliberative privilege protects, and Utah Medical presents no compelling countervailing reason for release of the redacted information.

Utah Medical raises one final argument, that release of the completed EIR's justifies disclosure of this redacted supporting information. This conclusion is in error, the release of the EIR does not warrant disclosure of the subjective information and opinions that went into the

creation of those EIR's. The deliberative process privilege applies to the redacted information in Documents 2, 3, and 7.

III. Documents 4, 5, & 6

Document 4 (dated June 12, 2002) is a memorandum from the Compliance Branch of the FDA's Denver District Office to the Division of Compliance, Office of Surveillance and Compliance in Centers for Devices and Radiological Health, which states the District's "recommendations"[26] about whether the agency should initiate an enforcement action against Utah Medical. Document 4 is signed by the District Director and Director of the District's Compliance Branch. The memorandum discusses and analyzes Utah Medical's past inspections and opines whether regulatory action is appropriate. The memorandum discusses the strengths and weaknesses of regulatory action. There are 25 attachments to this memorandum, two of which are draft pleadings that were not intended to reflect the agency's final position. Utah Medical does not seek these draft pleadings. Twelve of the remaining attachments have been provided to Utah Medical in the administrative record. The other eleven attachments have not been included in the record. Because Utah Medical has not raised a specific objection to the exclusion of these 11 exhibits – the court will only review the privilege as to Document 4, not the undisclosed remaining eleven exhibits.

Document 5 (dated December 16, 2002) is a memorandum from Mr. Weixel containing his recommendations to the FDA's Office of Chief Counsel as well as his evaluation, the 2003

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[26] Memorandum in support of Motion to Compel Production of Administrative Record Documents, p. 19.

EIR, and the April 15, 2002 FDA 483. This memorandum also discusses Utah Medical's history, the 2002 inspection, and Utah Medical's response to this inspection. The memorandum concludes with Mr. Weixel's recommendation regarding Utah Medical's status after the 2002 inspection.

Document 6 (dated January 10, 2003) is a memorandum from Mr. Weixel to the Office of Chief Counsel discussing the author's evaluation of the District's June 12, 2002 memorandum (Document 4). The memorandum includes Mr. Weixel's recommendations of whether the agency should pursue an enforcement action against Utah Medical. The memorandum also discusses his opinions and concerns regarding enforcement action against Utah Medical.

There are four attachments to Document 6. First, is the Inspectional Guidance – that is, Document 1 discussed above. Second is a chart prepared by Mr. Weixel that compiles the Quality System Regulation deviations from 1995 through 2002. Third is a series of emails between August 12 and 13, 2002 between Mr. Weixel and Harry Bushar, Ph.D., a statistician at the Center for Devices and Radiological Health. The emails discuss Dr. Bushar's opinions regarding his statistical review of the 2002 EIR. The final attachment is draft pleadings which were submitted to agency counsel and were not intended as the final position of the agency. The FDA asserts these attachments fall within the deliberative process privilege. Utah Medical has raised a specific objection only to Document 1. The court construes their silence on the remaining attachments as not contesting the FDA's assertion of privilege to these documents. Moreover, the court concludes that the deliberative privilege applies to Documents 4, 5 and 6, including the attachments.

Documents 4, 5, and 6 are all protected by the deliberative process privilege. Each of these documents was prepared to assist the FDA in determining whether to recommend an enforcement action against Utah Medical to the Department of Justice. All three of the documents are pre-decisional and deliberative.[27] These three documents are all pre-decisional because they occurred before the FDA determined whether to refer the matter to the Justice Department. The documents are deliberative because they refer to the formulation of the agency's policy regarding Utah Medical.[28] Utah Medical does not articulate any specific reasons as to how these documents are post-decisional or non-deliberative. Government deliberations regarding whether to initiate suits are clearly protected by the deliberative process privilege.[29]

Utah Medical raises three objections to the application of the deliberative process privilege to Documents 4, 5, and 6. First, that the "process" itself was flawed and thus these materials are not privileged. Second, the FDA waived any privilege; and third, the balancing test favors disclosure. [30] With respect to the first claim, Utah Medical argues that the decision-making process surrounding is the subject of this litigation and therefore the deliberative process privilege may not be raised.[31] Specifically they claim that two documents containing a computer error cast doubt on the enforcement recommendations. Utah Medical, however, did not raise a

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[27] *See Access Reports,* 926 F.2d at 1194-95.

[28] *See Hopkins*, 929 F.2d at 84.

[29] *See Farley,* 11 F.3d at 1389.

[30] Memorandum in Support of Motion to Compel Production of Administrative Record Documents, p. 22.

[31] *See Burka v. New York City Transit Authority,* 110 F.R.D. 660, 667 (S.D.N.Y. 1986).

claim for a faulty decision-making processes in its complaint in this case. Instead, it claimed that the agency decision was arbitrary and capricious in that the FDA applied the wrong standards in its determination of whether to issue the Certificates to Foreign Governments and that the FDA improperly based its decision on an erroneous conclusion that Utah Medical did not comply with the Good Manufacturing Practices regulations. More important, Utah Medical, cannot avoid the deliberative process privilege by the simple expedient of recast its complaint as a challenge to the decision-making "process." The FDA rightly notes that every suit challenging an agency's decision could be construed as a challenge to its decision-making process. An agency must always provide a rational and non-arbitrary basis for its conclusion. However, Utah Medical raised no specific objections to the process used by the FDA until the deliberative process privilege was asserted. Because Utah Medical has provided no specific information, apart from two trivial computer errors that demonstrate the deliberative process itself was at issue, no justification exists for penetrating the privilege.

Utah Medical also asserts that the FDA waived its deliberative process privilege because the April 1, 2003, decision indicated the enforcement action recommendation was based, in part, on the recommendations in Documents 4, 5, and 6. A limited reference to an enforcement action does not waive the contents of memoranda deliberating whether to recommend such an action.[32]

Finally, Utah Medical asserts that even if the privilege does apply, the balancing test favors disclosure of these documents. Utah Medical asserts that these three documents are the

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[32] *See, e.g., In re Sealed Case,* 121 F.3d at 741.

only justification for its April 1, 2003 decision denying Utah Medical's application. This argument falls flat for several reasons.

First, these documents were written well before Utah Medical's request for Certificates for Foreign Governments and for reasons having nothing to do with assessing its export certificate requests. Second, the decision to deny the export certificates was based on Utah Medical's failure to operate in substantial compliance with the Quality System Regulations, not these memorandum. Finally, the FDA explained its decision was based on June 2001, March 2002, and March 2003 inspections, which revealed the devices were not in compliance with the relevant standard. The 2001, 2002, and 2003 EIRs, the inspection findings, a fifteen-volume administrative record, the FDA 483's, and a six-hour meeting all provided Utah Medical with a factual basis as to the FDA's decision.

On the other side of the scales, these documents are the very type of documents this privilege is designed to protect. They are frank, subjective, and candid assessments of the situation at Utah Medical. Releasing these documents would chill honest, internal discussions by agency employees. Utah Medical's need for the documents does not outweigh the need for privilege.

Conclusion

Because the deliberative process privilege applies, the court DENIES the Motion to Compel the Production of Administrative Record Documents. The court therefore finds it unnecessary to reach the other reasons advanced by the government to deny the motion.

DATED this 31st day of March, 2004.

BY THE COURT:

Paul G. Cassell
United States District Judge

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United States District Court
for the
District of Utah
April 1, 2004

* * CERTIFICATE OF SERVICE OF CLERK * *

Re: 2:03-cv-00525

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